OFFICE OF THE SCIENCE ADVISOR

GUIDANCE

CHAPTER 7

ASSESSMENT OF HEALTH RISKS FROM INORGANIC LEAD IN SOIL

ABSTRACT

This guidance describes a mathematical model for estimating blood lead concentration resulting from contact with lead-contaminated environmental media. A lead concentration of concern of ten micrograms per deciliter of whole blood is established. A distributional approach is used, allowing estimation of various percentiles of blood lead concentration associated with a given set of inputs. The method has been adapted to a computer spreadsheet.

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Assessment of Health Risks From Inorganic Lead in Soil

1 INTRODUCTION

1.1 Purpose

The purpose of this guidance is to provide a methodology for evaluating exposure and the potential for adverse health effects resulting from exposure to lead in the environment.

1.2 Application

Since most human health effects data are based on blood lead (Pb) concentration, this guidance presents a blood Pb concentration of concern for the protection of human health, and an alogrithm for estimating blood Pb concentrations in children and adults based on a multi-pathway analysis.

1.3 Limitations

It is anticipated that this guidance will be periodically revised to reflect the changing state of the science.

2 PRINCIPLES

2.1 Blood Lead Concentration Of Concern

The Pb concentration of concern in children and adults is ten micrograms (ug) per deciliter (dl) of whole blood. The point of departure for risk management is a 0.01 risk of exceeding this value.

2.2 Lead Exposure Pathways--Blood Lead Calculation

This method can be used to estimate blood lead concentrations resulting from exposure via the five pathways listed below. Each pathway is represented by an equation relating incremental blood lead increase to a concentration in a medium, using contact rates and empirically determined ratios. The contributions via the five pathways are added to arrive at an estimate of median blood lead concentration resulting from the multipathway exposure. Ninetieth, ninety-fifth, ninety-eighth, and ninety-ninth percentile concentrations are estimated from the median by assuming a log-normal distribution with a geometric standard deviation (GSD) of

1.42. The method has been adapted to a computer spreadsheet.

3 METHODS

Generalized equations describing uptake via the five exposure pathways are as follows:

Dietary Intake Equation

Pbb = dietary Pb * contact rate * dietary constant

where:

dietary Pb (ug Pb/kg diet) = (9.45 + 0.025 * mg Pb/kg soil) [1]
contact rate, adults = 2.2 kg diet/day [2]
contact rate, children = 1.3 kg diet/day [2]
dietary constant, children = 0.16 (ug Pb/dl blood)/(ug Pb/day) [3]
dietary constant, adults = 0.04 (ug Pb/dl blood)/(ug Pb/day) [4]

Drinking Water Intake Equation

Pbb = water Pb * contact rate * dietary constant

where:

drinking water Pb (ug Pb/l water) is a site-specific, measured value [5]
contact rate, adults = 1.4 l water/day [6]
contact rate, children = 0.4 l water/day [6]
dietary constant, children = 0.16 (ug Pb/dl blood)/(ug Pb/day) [3]
dietary constant, adults = 0.04 (ug Pb/dl blood)/(ug Pb/day) [4]

Soil and Dust Ingestion Intake Equation

Pbb = soil Pb * contact rate * soil constant

where:

soil Pb (ug/g) is a site-specific, measured value [15]
contact rate, children = 0.055 g/day [7]
contact rate, adults = 0.025 g/day [8]
soil constant, children = 0.07 (ug Pb/dl blood)/(ug ingested Pb/day) [9]
soil constant, adults = 0.018 (ug Pb/dl blood)/(ug ingested Pb/day) [9]

Inhalation Intake Equation

Pbb = atmospheric Pb * inhalation constant

where:

atmospheric Pb = local or regional ambient Pb (ug/m3) + (airborne dust * soil Pb)10
inhalation constant, children = 1.92 (ug/dl)/(ug/m3)11
inhalation constant, adults = 1.64 (ug/dl)/(ug/m3)11
airborne dust (g/m3) is a site-specific, measured value with a default value

of 0.00005.

Dermal Contact Intake Equation

Pbb = soil Pb * contact rate * soil constant
where:

soil Pb (ug Pb/gm soil) is a site-specific, measured value
contact rate, children = 1.4 gm soil/day [12]
contact rate, adults = 1.85 gm soil/day [13]
soil constant = 0.0001 (ug Pb/dl blood)/(ug dermal Pb/day) [14]

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1 Derived as follows: (0.945 * 10 ug/kg) + (0.055 * 0.00045 * soil Pb in mg/kg * 1000 ug/mg). Assumes that 5.5% of the diet consists of home-grown produce with the other 94.5% supplied by a homogeneous source with a lead content of 10 ug/kg. If food production on the site can be ruled out, use 10 ug/kg for dietary lead (EPA, 1989b, Bolger, et.al., 1990). Home-grown produce is assumed to contain 0.045% of the lead level in the soil.

2 Based on a report by Pennington (1983). For this method, a one-year-old child shall represent all children, based on the assumption that protecting the one-year-old child will protect all children.

3 Based on a study by Ryu, et.al. (1983)

4 Based on a report by FDA (1990)

5 Pb concentrations in local water supplies as consumed. If site-specific data are unavailable, a value of 15 ug/l may be used.

6 EPA (1989b)

7 Based on Calabrese (1990). Deliberate soil ingestion (soil pica) is represented as 0.00079 kg soil/day average.

8 For residential exposures and most occupational exposures, based on Calabrese (1990). Occupations with a high potential for soil ingestion (such as construction) should be represented as 0 .00005 kg soil/day average.

9 These values are 44% of that for lead ingested with food or water, based on a study in rats which compared the bioavailability of lead acetate mixed with the diet to that of soil-bound lead (Chaney et.al., 1990).

10 The ambient air Pb concentration data are available from the California Air Resources Board, Technical Support Division. Data for the most recent year for the nearest monitoring station should be used. If monitoring data collected within the same air basin are unavailable, a value of 0.18 ug/m3 may be used, or consult with the DTSC project manager. Respirable airborne dust is assumed to be 0.00005 g/m3 unless site-specific data are available.

11 Based on EPA (1986)

12 Based on a soil adherence of 5 g/m2 and 0.28 m2 of exposed skin (EPA, 1989b).

13 Based on a soil adherence of 5 g/m2 and 0.37 m2 of exposed skin (EPA, 1989b).

14 This value is derived by multiplying the Pb ingestion:blood concentration ratio for adults (0.018 ug/dl per ug/day) by the ratio of dermal absorption [0.06% (Moore, et. al., 1980)] to oral absorption [11% (ATSDR, 1990)].

15 Developed according to Chapter 2 of this Guidance.

4 COMMENTS

4.1 Blood Lead Concentration Of Concern

The traditional reference dose approach to toxic chemicals is not applied to Pb because most human health effects data are based on blood Pb concentrations rather than external dose. Blood Pb concentration is an integrated measure of internal dose, reflecting total exposure from site-related and background sources. A clear no-observed-effect concentration has not been established for such Pb-related endpoints as birth weight, gestation period, heme synthesis and neurobehavioral development in children and fetuses, and blood pressure in middle-aged men. Dose-response curves for these endpoints appear to extend down to 10 ug Pb/dl or less (ATSDR, 1990).

4.2 Estimating Blood Lead Concentrations From Environmental Concentrations

Total Pb is generally used as the measure of Pb in various media, even though the disposition of Pb may differ according to its form. Insufficient data are available to justify differential treatment of different forms of inorganic Pb. However, if the lead at a particular site has been shown, in studies acceptable to DTSC, to be less bioavailable than the assumed values, lower bioavailability factors may be substituted for the default factors. Organic Pb is more readily absorbed through the skin and other membranes than inorganic Pb, and it must therefore be treated separately. Since it is less stable in the environment, it is usually a minor source of exposure.

In the absence of specific information about the population of interest, background exposures are estimated using norms developed from survey data.

4.3 Derivation Of Model Parameters

Unless the potential for on-site gardening can be ruled out, it is assumed that 5.5% of the diet consists of home-grown produce, based on EPA guidance (USEPA, 1991). Pb concentration in home-grown produce is calculated as 0.045% of that in the soil, based on plant uptake studies (Chaney, et.al., 1982). Background dietary Pb concentration (10 ug/kg) is based on a 1990 report based on FDA data (Bolger, et.al., 1990). The default drinking water Pb concentration is based on the federal action concentration of 15 ug/l at the tap (USEPA, 1991b).

The distribution of blood Pb concentrations for a given set of environmental inputs is a critical factor in protecting sensitive members of the population.

Based on a review of data from NHANES II and from several published studies of blood Pb concentrations in children living near point sources of lead, EPA concluded that blood Pb was generally log-normally distributed, that the geometric standard deviation (GSD) for children was between 1.3 and 1.53, and that 1.42 was a representative value for the GSD (USEPA, 1989c). Adult GSDs ranged from 1.34 to 1.40, which we do not consider to be sufficiently different from the range for children to justify using a different value for adults. The model assumes a log-normal distribution with a GSD of 1.42 and uses this information to estimate the fiftieth, ninetieth, ninety-fifth, ninety-eighth, and ninety-ninth percentile blood Pb concentration for a set of inputs. Since this distribution reflects the physiologic and behavioral variables including soil consumption, using upper bound values for contact rates would distort the percentiles corresponding to blood Pb concentrations.

The availability of Pb ingested with soil is based on a study which compared the absorption of soil Pb and Pb acetate incorporated into the diet of rats (Chaney, et.al., 1990). While the authors found a direct relationship between the Pb concentration in the soil and Pb bioavailability, the data did not define the shape of the concentration/ bioavailability curve sufficiently to allow extrapolation beyond the range studied. The highest observed bioavailability for soil lead concentrations less than 1000 ppm was 44% of that observed for Pb acetate, and this guideline adopts this value as a conservative estimate of bioavailability. To accurately assess the matrix effect, a variety of variables, including lead species, particle size, and soil type would have to be systematically examined at various Pb concentrations in soil.

The daily soil adherence to skin of 5 g/m2 (0.5 mg/cm2) is based on Driver et.al (1989). The dermal absorption factor of 0.0001 ug Pb/dl blood per ug dermal Pb/day was developed by multiplying the Pb ingestion:blood concentration ratio for adults (0.018 ug/dl per ug/day) by the ratio of dermal absorption [0.06% (Moore, et. al., 1980)] to oral absorption [(11% (ATSDR, 1990)]. Based on data in the Exposure Factors Handbook (USEPA, 1989b), the median skin area of arms, hands, feet, and legs of 1-year-old boys is estimated to be 0.28 m2, and the median skin area of arms and hands of men is estimated to be 0.37 m2.

The ratio of 0.16 ug/dl per ug/day ingested by children is a value derived from studies in infants by Ryu et.al. (1983). The ratio of 0.04 ug/dl per ug/day ingested by adults is an empirically-determined value recommended by EPA (1986) and FDA (1990). The default value for inadvertent soil/dust ingestion by children , 55 mg/day, is based on tracer studies reviewed by Calabrese, et.al. (1991). Adult soil consumption is 25 mg/day, based on EPA (1991a). DTSC uses soil consumption rates of 200 and 100 mg/day in calculating a reasonable maximum exposure for children and adults, respectively. However, reasonable maximum inputs are not recommended for use with the lead model because the model already considers the distribution of blood lead, which reflects variation in soil ingestion along with other variables. Soil consumption representing pica is 0.79 g/day, based on estimates by Calabrese et.al. (1991).

The slopes of 1.92 and 1.64 ug/dl of blood per ug/m3 of continuously-breathed air at atmospheric Pb concentrations <5 ug/m3 are based on results of experimental exposures and epidemiological studies which adjusted for airborne lead contributions to pathways other than inhalation. These studies found slopes ranging from 1.52 to 2.46 ug/dl per ug/m3 in children and 1.25 to 2.14 in adults (USEPA, 1986). The default airborne lead concentration is the highest monthly mean 24-hour value recorded in California in 1990.

4.4 Using This Guidance

This guidance may be implemented using a computer spreadsheet, which may be obtained from DTSC. The spreadsheet is based on DTSC Guidance, Volume 4, Chapter 1, which should be consulted for more general aspects of spreadsheet application. For this spreadsheet, soil concentration in mg/kg (ppm w/w) is entered in cell E7. The spreadsheet uses it in each calculation that is affected by soil Pb. Atmospheric Pb is entered in cell E6. Drinking-water Pb is entered in cell E8. If omission of the site-grown produce pathway can be justified, a "0" is entered in cell E9. Airborne dust level is entered in cell E10. The remainder of the cells are protected and should not be altered without approval of DTSC. Any such changes will require sufficient justification and must be documented.

4.5 Other Standards And Guidance

USEPA (1991c) considers lead to be a class B-2 carcinogen, with sufficient evidence in animals and inadequate evidence in humans. A carcinogenic potency has not been assigned. The federal MCL is 15 ug/l maximum at the tap with a maximum of 5 ug/l as a system-wide average (USEPA, 1991b). The Centers for Disease Control has stated that prevention activities should be directed at reducing children's blood Pb concentrations at least to below 10 ug/dl (CDC, 1991). The EPA has set 1.5 ug/m3 as the Pb concentration limit for ambient air (quarterly average) (USEPA, 1978). California's standard is also 1.5 ug/m3, but is based on a monthly average. The threshold limit value is 50 ug/m3 for workplace air (ACGIH, 1989).

FDA (1990) considers the Lowest Observable Adverse Effect Level (LOAEL) to be 10 ug/dl in children and fetuses, and 30 ug/dl in adults. They use empirically-derived ratios of 0.16 and 0.04 ug/dl per ug/day ingested to predict concentrations in young children and adults, respectively. Applying an uncertainty factor of ten results in provisional tolerable intake levels of 6 ug/day for children six or less, 15 ug/day for children over six, 25 ug/day for pregnant women, and 75 ug/day for men.

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